

Washington State Health Care Authority **Prescription Drug Program**

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Final Minutes of December 17, 2003 P&T Meeting [Approved by the committee at the March 17, 2004 meeting]

Committee Attendance:

Robert Bray, M.D.
Carol Cordy, M.D. (Vice Chair)
Daniel Lessler, M.D. (Chair)
T. Vyn Reese, M.D.
Angelo Ballasiotes, PharmD.
Alvin Goo, PharmD.
Jason Iltz, PharmD.
Janet Kelly, PharmD.
John White, PA, PharmD (Late arrival, early departure – Not absent for any P&T motions)
Patty Varley, ARNP

Quorum was shown for all Pharmacy & Therapeutics Committee motions, 2nd's, and votes.

9:00 a.m. - Committee came to order.

* Review of changes to Plan of Operations by Melodie Bankers, Director of Legal and Contract Services, Public Disclosure Officer for the Health Care Authority.

Motion: [Lessler] To accept the Plan of Operations with the changes to clarify the voting process explanation of majority in quorum Subsection N.4 (page 9).

2nd

Vote: Unanimous; Yea

❖ A full review was given by Marian McDonough, PharmD. with the Oregon Health and Sciences University w/ Kim Peterson (by phone conference).

Beta Adrenergic Blockers For the treatment of:

Hypertension

Unnamed rep for Astra Zeneca commented on there being different drugs in extended release tablets than those that are in standard tablets.

Motion: [Reese] Acebutolol, Atenolol, Bisoprolol, Carteolol, Carvedilol, Labetalol, Metoprolol, Metroprolol ER, Nadolol, Penbutalol, Pindolol, Propranolol, Propranolol ER, and Timolol are shown to be equal in safety and efficacy and no differences were shown in the special population for the treatment of Hypertension.

 2^{nd}

Vote: Unanimous; Yea

Angina

- Shymal Das for Astra Zeneca commented on exclusions in studies.
- * Siri Childs, PharmD. for MAA commented on MAA's concerns on how to manage this distinction.

Motion: [Goo] Atenolol, Bisoprolol, Carvedilol, Labetalol, Metoprolol, Metoprolol ER, Pindolol, and Propranolol are shown to be equal in safety and efficacy in treatment for the indication of Angina.

2nd

Vote: Unanimous; Yea

Post Coronary Artery Bypass Graft (Post CABG)

No stakeholder comments.

Motion: [Bray] To exclude Beta Adrenergic Blockers for the treatment of the indication of Post Coronary Artery Bypass Graft.

 2^{nd}

Vote: Unanimous; Yea

Silent Ischemia

❖ Unnamed rep for Astra Zeneca requested that more trials be included in the study.

Motion: [Bray] Poor evidence that any Beta Adrenergic Blockers be accepted to treat Silent Ischemia.

2nd

Vote: Unanimous; Yea

Recent Myocardial Infarction (Non LV Dysfunction)

- Shymal Das for Astra Zeneca commented regarding studies and mortality in Copernicus and 1 year later.
- * Ron Gallagher for Glaxo Smith Kline explained other study vs. Copernicus study and inclusions. Consideration of appropriate usage. (i.e.... auto approval with soft edits for patients on Ace Inhibitors.)
- Carol Cordy, M.D. (Vice Chair) stated that studies were all different, expressing difficulty in making a general motion.
- ❖ Marian McDonough, PharmD. for the Oregon Health and Sciences University explained the differences in the studies

Motion: [Bray] Atenolol, Carvedilol, Metoprolol, and Propranolol are shown to be equal in safety and efficacy in treatment for the indication of Recent Myocardial Infarction (Non Left Ventricular Dysfunction).

2nd

Vote: Unanimous; Yea

Congestive Heart Failure

- Ron Gallagher for Glaxo Smith Kline commented on mortality advantage information (i.e.... Copernicus Study)
- Dan Gattley, M.D. (Cardiologist) representing Glaxo Smith Kline commented that there is a lot of debate regarding Beta Blocker usage for this indication. Carvedilol having the most data, emphasizing the mortality data.
- Siri Childs, PharmD. for MAA stated that DSHS/MAA would have selective coverage with pre authorization for some usage with specific indications.

Motion: [Reese] Bisoprolol, Carvedilol, and Metoprolol ER are shown to be equal in safety and efficacy in treatment for the indication of Congestive Heart Failure.

Vote: Unanimous; Yea

Atrial Arrhythmia

❖ No stakeholder comments.

Motion: [Reese] Evidence approves the use of Atenolol, Metoprolol ER, Nadolol, and Pindolol to be equal in safety and efficacy in treatment for the indication of AA.

Vote: Unanimous; Yea

Migraine Headache

No stakeholder comments.

Motion: [Bray] For the indication of Migraine Headache, the P&T Committee considers Atenolol, Bisoprolol, Metoprolol, Metoprolol ER, and Pindolol as equal in safety and efficacy.

2nd

Vote: Unanimous; Yea

Bleeding Esophageal Varices

- Marian McDonough, PharmD. for the Oregon Health and Sciences University explained drugs included in the study.
- Daniel Lessler, M.D. (Chair) inquired if there was other evidence of indirect connection.
- ❖ Kim Peterson for the Oregon Health and Sciences University responded that there was not. Fair quality trials have been done.
- ❖ Jason Iltz, PharmD. inquired if there was any overwhelming data.
- Marian McDonough, PharmD. for the Oregon Health and Sciences University responded that mixed results were given.

Motion: [Bray] Consider for Bleeding Esophageal Varices, Atenolol, Nadolol, Pindolol, and Propranolol are shown to be equal in safety and efficacy.

 2^{nd}

Vote: Unanimous; Yea

Estrogen

For the treatment of:

Menopausal Symptoms

- ❖ Jeff Graham, M.D. consultant for HCA covered Estrogen Trials.
- Marian McDonough, PharmD. for the Oregon Health and Sciences University commented on trial coverage.
- Susan Reede, M.D. expressed concerns on Estradial, regarding no low dose availability, and with delivery routes and their alternatives. Commenting that choices should be offered to patients.
- Marcia Coleman, M.D. for Wyeth Pharmaceuticals commented that OHSU was a good review but failed to address combined therapy and dose.
- * Patricia Sudic for Affiliated Computer Services commented on ways to handle seniors with no oral dosage usage available. Requested that the cream be recognized and to add conversion tables.
- ❖ Marcia Coleman, M.D. for Wyeth Pharmaceuticals commented on issue of switching prescriptions.
- ❖ Marian McDonough, PharmD. for the Oregon Health and Sciences University commented that no comparisons were made regarding dose and DDT's.
- Susan Reede, M.D. commented on DDTPTS risk with biomarkers.

Motion: [Iltz] Conjugated Equine Estrogen (oral), Conjugated Equine Estrogen (vaginal), Conjugated Estrogen Synthetic, Esterified Estrogen, Estradiol (oral), Estradiol (vaginal), and Estropipate are shown to be equally efficacious in the treatment for the indication of Menopausal Symptoms. There is insufficient evidence available to compare the relative safety of the estrogen products. Recommend lowest dose possible for any of these drugs.

2nd

Vote: Unanimous; Yea

Bone Density

- Marcia Coleman, M.D. for Wyeth Pharmaceuticals commented on dosage information regarding Osteoporosis.
- ❖ T. Vyn Reese, M.D. inquired if WHI showed only risk in bone fracture.
- ❖ Marian McDonough, PharmD. for the Oregon Health and Sciences University responded, yes.
- ❖ Alvin Goo, PharmD requested clarification of fracture rates.
- Susan Reede, M.D. responded that it depended on the age group.

There was no motion regarding Estrogen for the treatment of Bone Density.

Proton Pump Inhibitors

- ❖ Jason Iltz, PharmD. inquired if studies on dosing included "with food", "without food", "when", etc.
- ❖ Marian McDonough, PharmD. for the Oregon Health and Sciences University responded, yes and no. There were a number of different studies.
- ❖ T. Vyn Reese, M.D. commented that he saw no difference in data with regards to OTC, recommending there is no need to change.
- ❖ Doug Stogsdill for Astra Zeneca commented that OTC is for heartburn, not for treatment.
- Lucia (no last name given) for Tapron Pharmaceuticals commented regarding indications on OTC's and drug interactions with OTC's.
- ❖ Doug Stogsdill for Astra Zeneca commented on dose efficacies.

Motion: [Reese] No evidence that any PPI is safer or more efficacious than another.

Vote: Unanimous; Yea

12:30 p.m. - Pharmacy & Therapeutics Committee Adjourned